AUG 0 9 2002 K010727

510(k) Premarket Notification Summary of Safety and Effectiveness Information	*Flexline™ Clamp* *August 8, 2002*

Device Name: *Flexline™ Clamp*
Common Name(s): Vascular Clamp
Classification Name: Clamp, vascular

Establishment Name & Registration Number:
Name: Novare Surgical Systems
Number: 2954739

Classification:
Title 21, Code of Federal Regulations,

§ Sec. 870.4450 Vascular clamp.
(a) Identification. A vascular clamp is a surgical instrument used to occlude a blood vessel temporarily.
(b) Classification. Class II (performance standards).

ProCode: DXC

Equivalent Device(s):
1. The "Cosgrove Clamp", K974769, produced by Allegiance Healthcare Corporation.
2. The Slimline™ (iNtrack™ Clamp Inserts), K992640, Novare Surgical Systems, Inc.

Description of the Device:
The ***Flexline™ Clamp*** is intended for use by surgeons to temporarily occlude blood vessels in cardiovascular, peripheral vascular, and general surgical procedures. The device is constructed in such a way that the shaft of the clamp may be rigid or flexible at the discretion of the user. The clamp uses existing soft polymer jaw inserts to protect vascular tissue.

Equivalent Device(s):
The Allegiance Cosgrove, Slimline (now iNtrack™), and Novare's vascular clamps are all used by surgeons to temporarily occlude blood vessels during cardiovascular, peripheral vascular, and general surgery. The device labeling supports the use of these devices in the disciplines of cardiac, peripheral vascular, and general surgery. All devices are substantially equivalent in terms of materials, design, use and function.

Applicant / Sponsor Name / Address:
Novare Surgical Systems, Inc.
10231 Bubb Road
Cupertino, CA 95014
408.873.3161

Contact Person:
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Submission Correspondent:
David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389
925.356.2640

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 9 2002

Novare Surgical Systems, Inc
Mr. David W. Schlerf
C/O Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, CA 94523-3389

Re: K010727
Trade Name: Flexline Clamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: II
Product Code: DXC
Dated: May 22, 2001
Received: May 24, 2002

Dear Mr. Schlerf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K010727

DEVICE NAME: Flexline Clamp

INDICATIONS FOR USE:

The Flexline Clamp is used to temporarily occlude a blood vessel during cardiovascular, peripheral vascular and gastrointestinal surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010727